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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: BEXTRA AND CELEBREX MARKETING AND SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	CASE NO. C 06 6192
JILL S. FIELDS, BRADLEY MADISON, THOMAS STREETER, Plaintiffs, vs. PFIZER, INC., PHARMACIA CORPORATION; G.D. SEARLE & CO.; Defendants.	**CIVIL COMPLAINT** CRB **DEMAND FOR JURY TRIAL**

JILL S. FIELDS, BRADLEY MADISON, and THOMAS STREETER , Plaintiffs, by and through their undersigned counsel, bring this action for damages against Defendants, PFIZER, INC., G.D. SEARLE & CO.; PHARMACIA COROPRATION., (hereafter "Defendants") for damages arising from Defendants'

design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe prescription anti-inflammatory drug Valdecoxib, trade name BEXTRA® ("BEXTRA").

I. PARTIES

1. Plaintiff JILL S. FIELDS is, and was at all relevant times, an adult resident citizen of the State of Texas. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs were the cause of any appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the Plaintiff's injuries at an earlier. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drugs are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Plaintiff BRADLEY MADISON is, and was at all relevant times, an adult resident citizen of the State of Texas. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs were the cause of any appreciable harm sustained by Plaintiff. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs were the cause of any appreciable harm sustained by Plaintiff. Plaintiff

could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the Plaintiff's injuries at an earlier. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drugs are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

3. Plaintiff THOMAS STREETER is, and was at all relevant times, an adult resident citizen of the State of Texas. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs were the cause of any appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the Plaintiff's injuries at an earlier. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drugs are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

4. Defendant PFIZER, INC. ("PFIZER") is a Delaware corporation with its principal place of business in New York, New York. On July

16, 2002 PFIZER announced its proposed acquisition of PHARMACIA CORPORATION ('PHARMACIA"). On April 16, 2003, PFIZER completed its $60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, PHARMACIA acted in all aspects as PFIZER's agent and alter ego. At all relevant times, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib, trade name BEXTRA® ("BEXTRA") throughout the United States.

5. Defendant G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.) ("SEARLE") is a Delaware corporation with its principal place of business in Illinois. In April 2000 SEARLE was acquired by PHARMACIA, and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER's acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib, trade name BEXTRA® ("BEXTRA") throughout the United States.

6. Defendant PHARMACIA is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April

2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib, trade name BEXTRA® ("BEXTRA") throughout the United States.

7. Valdecoxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name BEXTRA. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of BEXTRA.

8. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of BEXTRA, and advertised, promoted, marketed, sold and distributed BEXTRA as a safe prescription medication when, in fact, Defendants had reason to know, and did know, that BEXTRA was not safe for its intended purposes, for the patients for whom it was prescribed, and for whom it was sold; and that BEXTRA caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

9. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendant's predecessors in interest.

II. JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 and there is complete diversity of citizenship between Plaintiff and Defendants.

11. Venue is proper in this District pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in this district, thereby receiving substantial financial benefit and profits from sales of the dangerous product in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

12. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, BEXTRA.

13. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (throughout the United States) the aforementioned prescription drug. Defendants do substantial business throughout the United States

and within this District, advertise in this district, receive substantial compensation and profits from sales of BEXTRA in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants or those Defendant's predecessors in interest.

III. INTERDISTRICT ASSIGNMENT

14. Assignment to the Northern District of California, San Francisco Division, is proper pursuant to MDL-1699, Pretrial Order No. 2 dated December 13, 2005, as this action is related to *In Re: Bextra and CELEBREX Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

IV. FACTUAL BACKGROUND

A. Facts Regarding Plaintiff

15. Plaintiffs were prescribed, and took, BEXTRA.

16. As a direct and proximate result of using BEXTRA, Plaintiffs suffered strokes.

17. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's heart attack and initial injury unaware—and could not have reasonably

known or have learned through reasonable diligence—that such injury directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations or from Plaintiff's ingestion of BEXTRA.

18. Plaintiff used BEXTRA in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

COMMON FACTUAL ALLEGATIONS

19. Defendants are in the business of designing, manufacturing, and marketing pharmaceuticals.

20. Defendants, at all times relevant hereto, designed, manufactured and sold BEXTRA in the United States.

21. BEXTRA is in a class of drugs called non-steroidal anti-inflammatory drugs ("NSAIDs") with selective cyclooxygenase 2 inhibitory properties (COX-2 Inhibitor).

22. Defendants began selling BEXTRA in 2001.

23. On or about March 17, 2005, The New England Journal of Medicine reported on the dangers associated with BEXTRA based upon Defendants' internal data. In addition, based upon its own trials and due to BEXTRA's similarity to Vioxx, Defendants knew or should have known of the cardiovascular risks associated with BEXTRA well before September 30, 2004.

24. As of April 7, 2005, Defendants had refused to withdraw BEXTRA® from the market despite scientific studies documenting greater than triple the risk of heart attacks, strokes and death in connection with its use, and despite evidence that BEXTRA caused deadly skin reactions at substantially higher rates than comparable products.

25. As reported in the Wall Street Journal, on or about April 7, 2005, the United States Food and Drug Administration forced Defendants to pull BEXTRA from the market.

26. Defendants distributed BEXTRA by misleading the public about the safety of the product and by failing to adequately warn the users of the potential serious dangers, which Defendants knew or should have known would result its use. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to the public and physicians.

27. Defendants made hundreds of millions of dollars selling BEXTRA to the American public.

28. Defendants failed to adequately test BEXTRA prior to sale. Adequate testing would have shown that BEXTRA was dangerous, especially as labeled.

29. Defendants and their officers, agents and managers intentionally proceeded with the manufacturing and marketing of BEXTRA, knowing that persons would be exposed to life-threatening, undisclosed risks in order to make money at the expense of the safety of the American public.

30. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and Plaintiff.

31. As a direct and proximate result of Defendants' bad conduct, Plaintiff sustained permanent and debilitating injuries, pain and emotional distress.

FIRST CAUSE OF ACTION - FAILURE TO WARN

32. Plaintiffs repeat and incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

33. Defendants had a duty to adequately warn the public, physicians, and Plaintiffs of the risks associated with using BEXTRA.

34. Defendant knew or should have known about the serious, undisclosed risks of BEXTRA identified herein prior to the sale of BEXTRA to Plaintiff.

35. BEXTRA was under the exclusive control of Defendants, and was sold without adequate warnings regarding the many serious risks associated with its use.

36. Plaintiffs were injured as a direct and proximate result of Defendants' negligent and grossly negligent failure to adequately warn of the risks associated with BEXTRA.

37. Defendants sold BEXTRA in knowing, conscious, and deliberate disregard of the foreseeable harm caused by BEXTRA and in violation of their duty to provide an accurate, adequate, and complete warning concerning its use.

WHEREFORE, Plaintiffs respectfully request relief against Defendants for Defendants' failure to warn of the dangerous nature of BEXTRA.

SECOND CAUSE OF ACTION – DEFECTIVE DESIGN

38. Plaintiffs repeat and incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

39. Plaintiffs plead the doctrine of strict liability. Defendant is strictly liable to Plaintiff under Section 402A, Restatement (Second) of Torts, for the defective design of BEXTRA. At the time BEXTRA was designed, manufactured and sold by said Defendants, safer alternative designs existed, which included designs other than those actually used, that had they been selected by said Defendants, would have prevented or significantly reduced the likelihood of Plaintiff's injuries, and such designs were both economically and technologically

feasible at the time these products left the possession of said Defendants, and had they been used, would not have impaired the utility of the product.

40. BEXTRA was sold, distributed, supplied, manufactured, marketed, and/or promoted by Defendants, and was expected to reach and did reach consumers without substantial change in the condition in which it was manufactured and sold by Defendants.

41. At all times, Plaintiffs used BEXTRA for the intended or for a reasonably foreseeable purpose.

42. Plaintiffs were hurt as a proximate and producing result of the defective and unreasonably dangerous condition of BEXTRA.

43. Defendants' conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff.

WHEREFORE, Plaintiffs respectfully request relief against Defendants for the defective design and manufacture of BEXTRA.

THIRD CAUSE OF ACTION – FRAUD

44. Plaintiffs repeat and incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

45. At all material times, Defendants were engaged in the business of manufacturing, marketing, distributing, promoting, and selling BEXTRA. As

such, Defendants had a duty to disclose the risks associated with the use of BEXTRA.

46. Defendants made misrepresentations of material facts to, and omitted and/or concealed material facts from Plaintiffs and their prescribing physician regarding the risks associated with BEXTRA.

47. Such misrepresentations, omissions, and concealments of facts include, but are not limited to:

a. Failing to disclose, and/or intentionally concealing, the results of tests and studies showing the potential risks associated with the use of Defendants' product BEXTRA;

b. Failing to include adequate warnings with BEXTRA regarding the potential and actual risks and the nature, scope, severity, and duration of serious adverse effects of Defendants' BEXTRA;

c. Concealing and/or providing false or inaccurate information regarding the known risks associated with Defendants' product BEXTRA; and

d. Concealing the known incidents of serious skin reactions, exfolliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and cardiovascular injuries, as previously alleged herein.

48. Defendants' misrepresentations and omissions were made with knowledge of the falsity of those representations and/or with such utter disregard for truthfulness that knowledge may be inferred.

49. Plaintiffs were not aware of the falsity of the foregoing representations, nor were Plaintiffs aware that one or more material facts concerning the safety of Defendants' product had been concealed or omitted.

50. Defendants knew that the Plaintiffs were ignorant of these facts and did not have an equal opportunity to discover the truth about the dangers presented by BERTRA. Defendants intentionally concealed facts known to them, as alleged herein, in order to ensure increased sales.

51. Defendants intended to induce consumers such as Plaintiffs to take some action, among other things, to buy and ingest BEXTRA, by failing to disclose these facts.

52. In reliance upon Defendants' misrepresentations (and the absence of disclosure of the serious health risks), Plaintiffs ingested BEXTRA.

53. Had Plaintiffs known the true facts concerning the risks associated with BEXTRA, Plaintiffs would not have taken it.

54. The reliance upon Defendants' misrepresentations was justified because said misrepresentations and omissions were made by individuals and entities that were in a position to know the facts concerning BEXTRA.

55. As a direct and proximate result of Defendants' misrepresentations, and/or concealment, Plaintiffs suffered injury.

56. Defendants' conduct in concealing material facts and making the foregoing misrepresentations was committed with conscious or reckless disregard of the rights and safety of consumers such as Plaintiff.

WHEREFORE, Plaintiffs respectfully request relief against Defendants for Defendants' fraud.

FOURTH CAUSE OF ACTION - BREACH OF IMPLIED WARRANTY

57. Plaintiffs repeat and incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

58. Defendants manufactured, marketed, sold, and distributed BEXTRA.

59. At the time Defendants marketed, sold, and distributed BEXTRA for use by Plaintiff, Defendants knew of the purpose for which BEXTRA was intended and impliedly warranted it to be safe and fit for such use.

60. Plaintiffs and their prescribing physician reasonably relied on the skill, superior knowledge, and judgment of Defendants as to whether BEXTRA was safe and fit for its intended use.

61. Due to Defendants' wrongful conduct as alleged herein, Plaintiffs could not have known about the risks associated with BEXTRA until after they ingested the medication.

62. Contrary to the implied warranty, BEXTRA was not safe or fit for its intended use.

63. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiffs suffered injury and harm as previously alleged herein.

WHEREFORE, Plaintiffs respectfully request relief against Defendants for Defendants' breach of implied warranty.

FIFTH CAUSE OF ACTION - BREACH OF EXPRESS WARRANTY

64. Plaintiffs repeat and incorporate herein by reference the allegations made in the above Paragraphs.

65. Defendants expressly warranted that their products were safe and well accepted by patients and were safe. These warranties came in the form of:

a. Publicly made written and oral assurances of the safety and efficacy of BEXTRA;

b. Press releases, interviews and dissemination via the media of promotional information, for the sole purpose of which was to create an increased demand for Bextra;

c. Verbal assurances and the downplaying of any risks associated with BEXTRA;

d. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference;

e. Promotional pamphlets and brochures published and distributed directly to consumers, doctors, and the public; and

f. Advertisements, including but not limited to direct to consumer advertising.

66. BEXTRA did not conform to these express representations because it is not safe and has high levels of serious, life-threatening side effects.

67. As a direct and proximate result of the breach of said warranties, Plaintiffs were injured.

WHEREFORE, Plaintiffs respectfully request relief against Defendants for Defendants' breach of express warranty.

SIXTH CAUSE OF ACTION – NEGLIGENCE AND NEGLIGENCE *PER SE*

68. Plaintiffs repeat and incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

69. Defendant knew, or in the exercise of ordinary or reasonable care ought to have known, that BEXTRA was dangerous, unsafe, and highly harmful to Plaintiff's health, notwithstanding which:

a. Defendants negligently failed to design a reasonably safe product;

b. Defendants negligently failed to remove BEXTRA from the market;

c. Defendants negligently failed to fund and conduct medical and scientific studies to determine the risks of the overall safety of BEXTRA;

d. Defendants negligently failed to conduct sufficient testing on BEXTRA that would have shown that they had serious side effects, including, but not limited to the cardiovascular events described above;

e. Defendants negligently failed to conduct adequate post-marketing surveillance to determine the overall safety of BEXTRA;

f. Defendants negligently failed to accurately disclose the results of its post-marketing surveillance to advise the Plaintiff, consumers, and the medical community of the aforementioned risks to individuals when the drug were ingested;

g. Defendants negligently failed to take any reasonable precautions or exercise reasonable care to warn Plaintiffs and Plaintiffs' physicians of the potential risks and serious thrombotic and cardiovascular side effects of BEXTRA;

h. Defendants negligently failed to warn that BEXTRA should not be used in conjunction with any risk factors for these risks such as a family history of ischemic heart disease, or risk factors for ischemic cardiovascular disease; and,

70. Defendants were negligent *per se* in violating 21 C.F.R. §§ 1.21, 99.101, 201.56, 201.57, 202.1, 310.303, 314.70, 314.80, and 314.81 in that:

a. The labeling for BEXTRA failed to contain a proper, complete and sufficient warning serious risks as soon as there was reasonable evidence of their association with BEXTRA in violation of 21 C.F.R. §§ 1.21 and 201.57(e);

b. The labeling for BEXTRA failed to list all adverse reactions reasonably associated with the use of the drugs and with drugs in the same pharmacologically active and chemically related class in violation of 21 C.F.R. § 201.57(g)(1);

c. The "Adverse Reactions" section of the BEXTRA labeling failed to list first the most severe adverse reactions in violation of 21 C.F.R. § 201.57(g)(2);

d. The "Warnings" section of the BEXTRA labeling failed to identify potentially fatal adverse reactions in violation of 21 C.F.R. § 201.57(g)(3);

e. There was inadequate information for patients regarding use of BEXTRA in violation of 21 C.F.R. § 201.57(f)(2);

f. The labeling for BEXTRA was not informative and accurate, and it was false and misleading and/or promotional in part, in violation of 21 C.F.R. §§ 1.21 and 201.56(b);

g. Defendants failed to properly maintain records and make reports related to the clinical experience or other data to make or facilitate a determination of whether there were grounds to withdraw FDA approval of BEXTRA in violation of 21 C.F.R. § 310.303(a);

h. Defendants failed to promptly review all adverse drug experience information, including available scientific literature, and failed to develop adequate written procedures for the surveillance, receipt, evaluation, and reporting of post marketing adverse drug experiences to the FDA in violation of 21 C.F.R. § 314.80(b);

i. Advertising for BEXTRA did not contain a "[T]rue statement" of information, and was false, misleading, and failed to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended in violation of 21 C.F.R. § 202.1;

j. Defendants failed to report serious and unexpected adverse drug experience information as defined by 21 C.F.R. § 314.80(a), regarding BEXTRA to the FDA in some instances, and failed to report the information timely in others, in violation of 21 C.F.R. § 314.80(c)(1)(i);

71. Defendant negligently failed to warn Plaintiffs of the risk of adverse events, including death.

72. Defendants owed a duty to consumers of BEXTRA, including the Plaintiffs, to use reasonable care in designing, testing, labeling, manufacturing, marketing, supplying, distribution and selling BEXTRA, including a duty to ensure that BEXTRA did not cause users to suffer from unreasonable, unknown, and/or dangerous side effects.

73. Defendants knew or should have known that consumers such as Plaintiffs would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

74. Defendants continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious and/or negligent disregard of the foreseeable harm caused by BEXTRA.

75. By virtue of Defendants' negligence, Defendants directly, foreseeably and proximately caused Plaintiffs to suffer injury.

WHEREFORE, Plaintiffs respectfully request relief against Defendants for Defendants' negligence.

SEVENTH CAUSE OF ACTION - GROSS NEGLIGENCE

76. Plaintiffs repeat and incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

77. Defendant's conduct was more than momentary thoughtlessness, inadvertence, or error of judgment. Such acts or omissions constituted such entire want of care as to establish that the acts or omissions were the result of actual conscious indifference to the rights, safety, or welfare of the person or persons affected.

78. Defendants continued to design, manufacture, market, and sell BEXTRA so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the harm inflicted on the consuming public.

WHEREFORE, Plaintiffs respectfully request relief against Defendants for Defendants' gross negligence, including an award of exemplary and punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief, in an amount exceeding the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter, as follows:

a. Pain and suffering in the past and future.

b. Mental anguish in the past and future.

c. Medical expenses in the past and future.

d. Physical impairment.

e. Exemplary damages.

f. Lost earnings and earning capacity in the past and future

g. Pre- and post-judgment interest.

h. Court costs.

i. All other relief the Court deems appropriate.

WHEREFORE, Plaintiffs demand judgment against defendants in an amount to be determined upon the trial of this action, together with the costs and disbursements of this action.

Dated: September 29, 2006

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial as provided by rule 38(a) of the *Federal Rules of Civil Procedure*.

Dated: September 29, 2006

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